K061396 Page 1 of 2

B - Administrative Information

1 510(k) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of the Premarket Notification in compliance with 21CFR. Part 807, Subpart E, Section 807.92

1) Submitter's name, address, telephone number, contact person

Lynn Harmer, Regulatory Submissions Manager
Philips Ultrasound, Inc.
P.O. Box 3003
Bothell, WA 98041-3003
Telephone: (425) 487-7312
Facsimile: (425) 487-8666
E-mail: Lynn.Harmer@philips.com

MAY 3 0 2006

Date prepared: 9 May 2006

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/Usual Name: Picture Archiving and Communications Systems Workstation

Proprietary Name: QLAB Quantification

Classification Name: Picture Archiving and Communications System, Class II

3) Device Description

The Parametric Imaging feature is an addition to the existing Cardiac 3DQ Advanced Plug-in already described on the iE33 510(k) submission K042540. The QLAB 5.0 3DQA plug-in Parametric Imaging provides the user with easy-to-use color-coded representations of regional left-ventricular (LV) segmental Timing and Excursion parameters displayed on the standard AHA/ASE 17-segment Bull's-eye display. The Parametric display may be used in assisting the clinician to visualize directly LV regional function in a user-friendly format.

4) Performance Standards

No performance standards for PACS systems or components have been issued under the authority of Section 514. The QLAB software has been designed to comply with the following voluntary standards:

- MSDN - Microsoft Developer's Network October 2001
- ISO Joint Photographic Experts Group (JPEG) Image Compression Standard

5) General Safety and Effectiveness Concerns

The device labeling contains operating instructions for the safe and effective use of the QLAB software.

6) Substantially Equivalent Devices

Philips Ultrasound believes that the QLAB 5.0 software with 3DQA plug-in is substantially equivalent to other commercially available products, specifically TomTec Image-Arena and Research-Arena applications with 4D LV-Analysis 2.x module (K040546).

7) Software

Software development for the QLAB software follows documented processes for software design, verification and validation testing. A risk assessment has been completed to identify potential design hazards that could cause an error or injury based on the use of the quantification results. Appropriate steps have been taken to control all identified risks for this type of image display and quantification product.

8) Conclusions

The QLAB software is designed and manufactured to meet United States and international standards for the display and quantification of images acquired on Phillips Ultrasound devices. The system is designed to incorporate components common to all image viewing systems for the display, manipulation and quantification tasks within a clinical setting. The QLAB software incorporates features of predicate devices cleared through premarket notification and no new issues of safety or effectiveness are raised.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 30 2006

Philips Medical Systems
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K061396
Trade/Device Name: QLAB Quantification Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 17, 2006
Received: May 19, 2006

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. FDA Indication for Use Form

510(k) Number: K061396

Device Name: QLAB 5.0 Quantification Software with Cardiac 3DQ Advanced plug-in including Parametric Imaging.

Indications for Use: QLAB Quantification software is a software application package. It is designed to view and quantify image data acquired on Philips Medical Systems ultrasound products.

Prescription Use: __X_____ OR **Over-The-Counter Use:** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061396